

III. REMARKS

United States Serial No. 10/555,727 was filed on November 7, 2005. The present patent application is a national stage patent application of International Application No. PCT/EP2004/000270 filed 5 May 2004. Claims 1-20 are pending. In view of the remarks set forth herein, Applicants respectfully request favorable reconsideration of the application, and earnestly solicit allowance of claims 1-20.

Claim Objections

Claims 9 has been objected to because the spelling of "colouring matter" is allegedly not an acceptable United States spelling. Applicants respectfully traverse the objection.

Examiners should not object to the specification and/or claims in patent applications merely because applicants are using British English spellings (e.g., colour) rather than American English spellings. (See MPEP §608.01). It is not necessary to replace the British English spellings with the equivalent American English spellings in the U.S. patent applications. *Id.* Note that 37 CFR 1.52(b)(1)(ii) only requires the application to be in the English language. There is no additional requirement that the English must be American English. Accordingly, Applicants respectfully request withdrawal of the objection to claim 9.

35 U.S.C. §102

Claims 1-5, 8, 10-12, 15-16, and 20 have been rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,266,335 to Cherukuri et al. It is specifically alleged that Cherukuri et al. teach matrix particles comprising a discontinuous phase of a plurality of inclusions of oil, wherein the oil is optionally flavor oil or fragrance oil, the oil is dispersed with in a matrix, the matrix comprising a cross-linked polymer and at least one filler (e.g., gum arabic).

Applicants respectfully traverse this rejection. "A finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device." *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1349 48 USPQ2d 1225, 1230 (Fed. Cir. 1998). Cherukuri et al. disclose spheroidal microcapsules containing oil and resin. (See Abstract, Column 2, lines 57-65). The disclosure in Cherukuri et al. demonstrates that the capsules differ significantly from Applicants' claimed subject matter. Cherukuri et al. specifically provide for "microencapsulated flavoring agents in the form of spheroidal microcapsules which comprise a core of peppermint oil and the glycerol ester of partially hydrogenated wood rosin (i.e., a type of resin) ..." (See Column 3, lines 11-14). Cherukuri et al. do not disclose matrix particles containing a plurality of inclusions of oil (i.e., akin to the multitude of seed casings contained with the outer covering of the pomegranate fruit) as is presently claimed. Cherukuri et al. rather disclose capsules that contain merely one oil core surrounded by a wall (i.e., a "coating layer"). (See Abstract, Column 3, lines 11-16).

Page 3 of the Office Action also alleges that Cherukuri et al. teach matrix particles comprising a filler (e.g., gum arabic) selected from the group consisting of inorganic substances, organic substances, and combinations thereof. However, Applicants respectfully submit that this assertion is contrary to the disclosure of Cherukuri et al. and the definition of a filler provided in Applicants' specification.

Unlike Cherukuri et al., Applicants' Claim 1 recites that the matrix comprises "at least one filler." Cherukuri et al. do not specify the provision of a filler. The Detailed Description of Cherukuri et al. specifically provides that the capsule simply "comprises (A) a core ... and (B) a coating layer over the core which comprises in percentages by weight of the coating layer ... gum arabic in an amount from about 45% to about 49% ..." (See Column 3, lines 20-35). Cherukuri et al. fail to mention, let alone disclose, the utilization of any filler in their application.

Applicants, however, disclose “fillers that are inert, essentially **insoluble** and essentially do not swell, and are capable of forming a dispersion of solid particles in water. These materials include non-starch polysaccharides, celluloses, modified starches, and other polymers, including proteins, such as zein.” (See Specification, page 4, lines 26-29, and claims 1, 6, and 11-16) (emphasis added). Based upon the definition of “filler” corresponding to an insoluble substance as provided in Applicants’ specification, gum arabic in Cherukuri et al. cannot be considered as such because gum arabic is extremely soluble in water. Therefore, the provision of gum arabic in Cherukuri et al. does not comply with the Applicants’ definition of a filler.

Applicants wish to avoid any confusion between the resins disclosed in Cherukuri et al. and the fillers utilized in Applicants’ invention. Specifically, the resins disclosed in Cherukuri et al. are added to the oil and not to the polymer matrix as in Applicant’s claims. (See Abstract, Column 3, lines 11-16). This is precisely the reason why the list of resins and fillers that are claimed by Applicants do not overlap (i.e., the resins are soluble in water and the fillers are not).

The Office Action further alleges that Cherukuri et al. teach that encapsulated flavors may be formulated in effective amounts with conventional additives, such as pharmaceutically acceptable carriers or confectionary agents (i.e. pharmaceutical carriers can also be added as fillers to the encapsulated flavor matrix). The express language in Cherukuri et al. cannot be ignored. As additionally distinguishing Cherukuri et al. from the claimed subject matter, Cherukuri et al. disclose that once prepared, the flavored capsules may be formulated in effective amounts with conventional additives, such as pharmaceutically acceptable carriers or confectionary ingredients in order to prepare a wide range of products. (See Column 7, lines 46-51). Consequently, adding pharmaceutical carriers to the polymer matrix is not disclosed in Cherukuri et al.

The subject matter of claim 1 is novel over Cherukuri et al. as this reference does not disclose matrix particles comprising a discontinuous phase of a plurality of inclusions of oil, wherein the oil is optionally flavor oil or fragrance oil, the oil dispersed within a matrix, the matrix comprising a cross-linked polymer and at least one filler. Accordingly, Cherukuri et al. do not anticipate the subject matter of claim 1 and the claims depending therefrom.

Claims 2-5, 8, 10-12, 15-16, and 20 ultimately depend from independent claim 1 and therefore include all of its features. Applicants therefore respectfully request that the rejection of claims 1-5, 8, 10-12, 15-16, and 20 under 35 U.S.C. §102(b) as being anticipated by USPN 5,266,335 to Cherukuri et al. be withdrawn.

35 U.S.C. §103

Claims 7, 13-14, and 17-19 have been rejected under 35 U.S.C. §103(a) as obvious over Cherukuri et al. Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) there must be (1) a suggestion or motivation to modify a reference, (2) a reasonable expectation of success, and (3) the modification of the reference must teach or suggest all claimed limitations. *In re Vaeck*, 947 F.2d 488 (Fed.Cir. 1991). Applicants respectfully submit that the reasons of record in the Office Action fail to establish all three elements of a *prima facie* case of obviousness under 35 U.S.C. §103(a). Because the Office Action fails to establish all elements of a *prima facie* case of obviousness under 35 U.S.C. §103(a), the rejection under 35 U.S.C. §103(a) should be withdrawn.

Claims 7, 13-14, and 17-19 depend from claim 1. The deficiencies of Cherukuri et al. with respect to disclosure of the features of claim 1 have been addressed above, and are incorporated herein.

With respect to claims 13-14, Cherukuri et al. do not disclose, suggest, or provide motivation for bulking agents such as mineral adjuvants which may serve as fillers and textural agents. Cherukuri et al. strictly teach that the amount of inventive encapsulated flavoring agent employed in an edible composition is dependant upon the type of bulking agent or carrier utilized in the composition. (See Column 7, lines 58-62). Therefore, Cherukuri et al. do not teach matrix particles as disclosed by Applicants or even hint that a filler should be added to the wall of such a particle.

In regard to claims 7 and 17-19, the Office Action also contends that one of ordinary skill would have been motivated to modify Cherukuri et al. and disclose the amount of surface oil at least for the purpose of quantifying the level of excess oil contained in the matrix. The Office Action avers that one would have been further motivated to quantify the amount of surface oil in an encapsulated matrix at the time of preparation and several times during storage to determine the storage stability of the matrix comprising the flavor oil. Applicants respectfully traverse this rejection.

Cherukuri et al. fail to provide any reference to "surface oil" whatsoever. Although Cherukuri et al. disclose that the size of the pores in the walls of the capsules may be controlled by the rate of the gelling process, such that encapsulated oil will not escape through the capsule walls, there still exists no explanation as to the location (i.e., surface of the particles) where one would attempt to quantify the potential lack of any oil released from the capsules. There is simply no disclosure, suggestion, or motivation in Cherukuri et al. that teach making the capsules as recited in claim 1 in a manner that results in surface oil below 10 % (wt/wt). Thus, Applicants respectfully submit that claims 7 and 17-19 are allowable over Cherukuri et al., and request that the 35 U.S.C. §103 rejection of claims 7 and 17-19 be withdrawn.

Claim 6 has been rejected under 35 U.S.C. §103(a) as being as being unpatentable over Cherukuri et al. in view of Huzinec et al. (United States Patent No. 5,912,030). Applicants respectfully traverse the rejection.

It is alleged that Cherukuri et al. disclose the claimed matrix particles, except that Cherukuri et al. are silent as to the matrix particles comprising microcrystalline cellulose (MCC) as filler. However, it is also alleged that Huzinec et al. teach microcrystalline carrier material, including MCC which can be mixed with additives, such as flavors, flavor enhancers, flavor masking additives, sweeteners, sweetener enhancers, vitamins, pharmaceuticals, minerals, colors, acids, and mixtures thereof, and that it would have been obvious to one of ordinary skill to modify Cherukuri et al. in view of Huzinec et al. and add microcrystalline cellulose to the matrix comprising the encapsulated flavor. Applicants respectfully traverse.

Cherukuri et al. has been discussed in detail above with respect to claim 1, from which claim 6 depends.

The Office Action identifies certain features of the claimed matrix particles which are allegedly disclosed by Cherukuri et al., but expressly and unequivocally concedes that Cherukuri et al. do not disclose or suggest matrix particles comprising MCC as claimed in the present application. Furthermore, Cherukuri et al. do not provide any suggestion or motivation to utilize MCC as filler.

Because the product of Cherukuri et al. does not disclose the claimed features of matrix particles comprising MCC, the presently claimed product is not substantially the same as the product of Cherukuri et al. Furthermore, the combination of Cherukuri et al. with Huzinec et al. does not arrive at the presently claimed subject matter, because this combination of references does not show all of the claimed features of claim 6, as discussed above with regard to claim 1.

Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

For the combination of Cherukuri et al. and Huzinec et al. to have been obvious at the time of the invention, a person of ordinary skill in the art would have needed some reason upon which to base an expectation of success. A reasonable expectation does not exist in this case. Huzinec et al. is directed to utilization of cellulose as a delivery system. (See Column 2, lines 8-19). In sharp contrast, Applicants claim cellulose as part of the matrix particles. (See Specification, page 4, lines 4 and 26-27, page 9, lines 17-19, and claims 6 and 12). Huzinec et al. clearly discloses that a “beneficial property of the carrier is the ability to incorporate into the carrier, by absorption and/or adsorption, the additives [e.g., flavors] and segregate them from one another, thereby allowing additive/carrier blends containing more than one additive to release each additive at the same or at different times.” (See Column 2, lines 8-12). “Examples of carriers [in Huzinec et al.] are **microcrystalline cellulose** ...” (See Column 2, lines 15-16) (emphasis added). Again, Huzinec et al. do not teach matrix particles as disclosed by Applicants or even hint that a filler, such as MCC, could or should be added to the wall of such a particle. Therefore, there is no reasonable basis upon which the cited art would lead one to focus on these compounds and suggest the manner in which to modify them in order to obtain the claimed matrix particles.

In fact, Huzinec et al. teach that “[e]ncapsulation of additives such as flavors and sweeteners is time-consuming and expensive.” (See Column 1, lines 37-38). Accordingly, Huzinec et al. actually teach away from the present claims. The Supreme Court in *KSR*, in discussing *United States v. Adams*, 383 U.S. 39 (1966), stated: “when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be non-obvious.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

Post-KSR cases support the longstanding proposition that a prior art “teaching away” from the claimed invention will support a finding of non-obviousness. For instance, in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), decided after *KSR*, the Federal Circuit rejected an “obvious to try” argument. Alphapharm argued that it was obvious to select “compound b” and modify it to arrive at the claimed invention. Takeda demonstrated that compound b was one of hundreds of millions of compounds disclosed in the art and that references taught away from its use.

For the aforementioned reasons, there can have been no reasonable expectation of success in combining Cherukuri et al. and Huzinec et al. at the time the invention was made, such that the combination of Cherukuri et al. and Huzinec et al. cannot properly support an obviousness rejection. Applicants respectfully request that the obviousness rejection as applied to claim 6 be withdrawn.

Claim 9 has been rejected under 35 U.S.C. 103(a) as being obvious over Cherukuri et al. in view of United States Patent No. 4,515,769 to Merritt et al. It is alleged that Cherukuri et al. teach the claimed matrix particles comprising flavor oil, a cross-linked polymer, and at least one filler for adding to foods and pharmaceuticals, except that Cherukuri et al. are silent as to the matrix particles comprising coloring matter. However, the Office Action on page 8 specifically alleges that Merritt et al. teach encapsulated flavorant material comprising coloring material, and therefore contends it would have been obvious to one of ordinary skill to modify Cherukuri et al. in view of Merritt et al. and add color to the encapsulated flavor. Applicants respectfully traverse.

Cherukuri et al. has been discussed in detail above with respect to claim 1, from which claim 9 depends.

With respect to claim 9, the Office action makes no specific allegations as to why the combination of Cherukuri et al. and Merritt et al. is obvious. “[O]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under § 103, teachings of references can be combined only if there is some suggestion or incentive to do so.” *ACS Hospital Systems, Inc., v. Montefiore Hospital*, 221 USPQ 929, 932, 933 (Fed. Cir. 1984). The Office Action cites column 3, lines 20-35, column 4, lines 16-21, column 6, lines 64-65, and column 8, lines 39-47 of Cherukuri et al. and column 11, lines 17-20 of Merritt et al. To support the rejection, Applicants have critically reviewed the Merritt et al. reference but have failed to uncover any teaching or suggestion that technology relating to encapsulated flavorant compositions comprising coloring material can be applied to matrix particles. Also, Merritt et al. do not disclose, suggest, or provide motivation for the creation of matrix particles as disclosed by Applicants’ or even hint that a filler can be added to the wall of such a particle. Accordingly, motivation to combine, as stated in *ACS Hospital Systems*, requires some suggestion in the reference to do so. Applicants submit that any combination of Cherukuri et al. and Merritt et al. is improper and therefore a prima facie case of obviousness may not be established. Therefore, Applicants respectfully request that the obviousness rejection as applied to claim 9 be withdrawn.

Applicants have addressed the instant rejections with respect to the independent claim in particular, and have distinguished the applied references as discussed above. It is therefore deemed unnecessary to address specific allegations of the Office Action regarding the dependent claims. Applicants therefore traverse these allegations, and do not concur with the same either explicitly or implicitly by not refuting each individually.

Double Patenting

Claims 1, 4, 8, and 11 have been provisionally rejected on the ground of nonstatutory obviousness-type double-patenting as being unpatentable over claims 1 and 6 of United States Patent No. 6,325,951 to Soper et al. ('951). Pages 9 of the Office Action alleges that the

supposed conflicting claims are not patentably distinct from each other because both inventions are addressed to flavor oil encapsulation in a matrix of colloids.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to a joint research agreement as set forth in 35 U.S.C. §103 (c)(2) and (3), when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000). Applicants respectfully submit that the obviousness-type double patenting rejection is improper in that Claims 1, 4, 8, and 11 are patentably distinct from Claims 1 and 6 in '951.

A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. §103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d

1839, 1846 (Fed. Cir. 1992). Applicants respectfully disagree that Claims 1, 4, 8, and 11 are obvious variations of Claims 1 and 6 in '951.

Claims 1, 4, 8, and 11 of the present application relate to matrix particles comprising a discontinuous phase of a plurality of inclusions of oil, wherein the oil is optionally flavor oil or fragrance oil, the oil dispersed within a matrix, the matrix comprising a cross-linked polymer and at least one filler. The claimed subject matter addresses the problem of surface oil associated with previously known matrix particles. High surface oil is a particular problem for such matrix particles because when the matrix material is cross-linked, it essentially contracts and results in oil being squeezed out of the particles. Claims 1 and 6 in '951, on the other hand, provide a method of enzymatically protein-encapsulating oil particles by complex coacervation.

'951 claims first forming a complex coacervate of oil particles with two oppositely-charged colloids; cooling said complex coacervate to a gel temperature at a pH of about 5 to deposit a protein shell around each of said oil particles; further cooling said complex coacervate to a cross-linking temperature below said gel temperature at a pH of about 7 to stabilize said protein shell; and adding an enzyme to the water for enzymatically cross-linking said stabilized protein shell at about pH 7 to form stable protein-encapsulated oil particles. Applicants' claims do not require cooling its matrix particles to a gel temperature at a pH of about 5 to deposit a protein shell around each of said oil particles. Nor do Applicants' claims require further cooling to a gel temperature at a pH of about 7 to stabilize said protein shell and adding an enzyme to the water for enzymatically cross-linking said stabilized protein shell at about pH 7 to form stable protein-encapsulated oil particles. In addition, the method disclosed in '951 is applicable to various types of particles, whereas the present claims are directed to specific matrix particles. Therefore, a nonstatutory obviousness-type double patenting rejection is not appropriate, since the Applicants' claims are patentably distinct from the reference claims and cannot be considered obvious over the reference claims.

Accordingly, Applicants respectfully request that the nonstatutory obviousness-type double patenting rejection based on claims 1 and 6 of USPN 6,325,951 as applied to claims 1, 4, 8, and 11 be withdrawn.

Claims 1, 4, 6, 8, and 10-12 have been provisionally rejected on the ground of nonstatutory obviousness-type double-patenting as being unpatentable over claims 1, 6, 9, 11-13, 16, 20-21, 23-25, and 28 of United States Patent No. 6,106,875 to Soper et al. ('875). Pages 9 of the Office Action alleges that the supposed conflicting claims are not patentably distinct from each other because both inventions are addressed to flavor oil encapsulation products and methods of making such products comprising a matrix of colloids or gels that may be proteins or carbohydrates. Applicants respectfully traverse the allegation that present Claims 1, 4, 6, 8, and 10-12 are obvious variations of Claims 1, 6, 9, 11-13, 16, 20-21, 23-25, and 28 in '875.

Applicants respectfully submit that the obviousness-type double patenting rejection is improper in that Claims 1, 4, 6, 8, and 10-12 are patentably distinct from Claims 1, 6, 9, 11-13, 16, 20-21, 23-25, and 28 in '875.

Claims 1, 4, 6, 8, and 10-12 relate to matrix particles comprising a discontinuous phase of a plurality of inclusions of oil, wherein the oil is optionally flavor oil or fragrance oil, the oil dispersed within a matrix, the matrix comprising a cross-linked polymer and at least one filler, wherein the filler comprises cellulose polymers or derivatives thereof. As previously discussed, the claimed subject matter addresses the problem of surface oil associated with previously known matrix particles. Claims 1, 6, 9, 11-13, 16, 20-21, 23-25, and 28 in '875, on the other hand, provide a method of encapsulating a volatile flavor or fragrance compound.

'875 claims first preparing a microcapsule having a hydrogel shell surrounding an oil core for retention of the oil in the shell, adding the compound in its gaseous state in the presence of water to the microcapsule for transportation of the compound into the retained oil core, transporting the compound by aqueous diffusion through the hydrogel shell into the

retained oil core, and retaining the oil core in the hydrogel shell during said transportation to provide the encapsulated compound in the hydrogel shell containing the retained oil core. Applicants' claims do not require preparing a microcapsule having a hydrogel shell surrounding an oil core for retention of the oil in the shell. Applicants' claims do not require either adding the compound in its gaseous state in the presence of water to the microcapsule for transportation of the compound into the retained oil core, nor do they require transporting the compound by aqueous diffusion through the hydrogel shell into the retained oil core, and retaining the oil core in the hydrogel shell during said transportation to provide the encapsulated compound in the hydrogel shell containing the retained oil core. In addition, the method disclosed in '875 is applicable to various types of particles, whereas the present claims are directed to specific matrix particles. Therefore, a nonstatutory obviousness-type double patenting rejection is not appropriate since the Applicants' claims are patentably distinct from the reference claims and cannot be considered obvious over the reference claims.

Accordingly, Applicants respectfully request that the nonstatutory obviousness-type double patenting rejection based on claims 1, 6, 9, 11-13, 16, 20-21, 23-25, and 28 of USPN 6,106,875 as applied to claims 1, 4, 6, 8, and 10-12 be withdrawn.

Conclusion

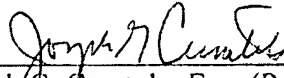
In view of the above remarks, Applicants respectfully request reconsideration of the application, withdrawal of the claim objections, the rejections under 35 U.S.C. §§ 102 and 103, and the nonstatutory obviousness-type double patenting rejections, and request the issuance of a formal Notice of Allowance directed to claims 1-20.

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Should the Examiner have any questions regarding the present amendments and remarks, Applicants' undersigned attorneys would welcome a telephone call.

Respectfully submitted,



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